

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 September 2001 (07.09.2001)

PCT

(10) International Publication Number
WO 01/64142 A1

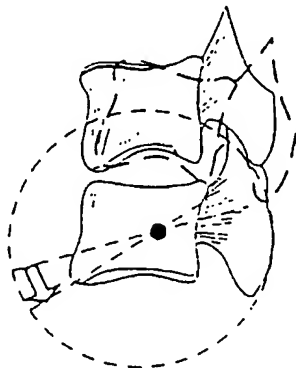
- (51) International Patent Classification⁷: **A61F 2/44**
- (21) International Application Number: **PCT/US01/06193**
- (22) International Filing Date: **27 February 2001 (27.02.2001)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
09/513,954 **28 February 2000 (28.02.2000)** **US**
- (71) Applicant (*for all designated States except US*): **CAUTHEN RESEARCH GROUP, INC.** [US/US]; Suite One, 6510 N.W. 9th Boulevard, Gainesville, FL 32605 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (*for US only*): **CAUTHEN, Joseph, C.** [US/US]; 8224 S.W. 28th Place, Gainesville, FL 32607 (US).
- (74) Agents: **BLUM, Seth et al.**; Saliwanchik, Lloyd & Saliwanchik, Suite A-1, 2421 N.W. 41st Street, Gainesville, FL 32606 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **ARTICULATING SPINAL IMPLANT**



(57) Abstract: An articulating spinal implant for intervertebral disc replacement. The articulating spinal implant is formed from two elements (20, 22), each engaging one of an adjacent pair of vertebra. An articulating means (24) between the two elements resists compression and lateral movement between the vertebra, but allows the adjacent vertebra to articulate about an instantaneous axis of rotation (44).

WO 01/64142 A1

DESCRIPTIONARTICULATING SPINAL IMPLANT5 Cross-Reference to a Related Application

This application is a continuation-in-part of co-pending patent application Serial No. 09/389,758, filed September 2, 1999, which is a continuation-in-part of co-pending patent application Serial No. 09/298,524, filed April 23, 1999, which is a continuation-in-part of patent application Serial No. 09/065,816, filed April 23, 1998, now issued on February 1, 2000 as U.S. Patent No. 6,019,792.

10Background of the InventionField of the Invention:

The invention relates generally to spinal implants for use in intervertebral disc replacement; and more specifically relates to articulating implants that fuse to adjacent vertebra by bone ingrowth, thus restoring proper intervertebral spacing, and eliminating nerve root and/or spinal cord compression, while preserving spinal flexibility.

15Description of Related Art:

The spinal column is formed from a number of vertebra, which in their normal state are separated from one another by cartilaginous intervertebral discs. These discs form a cushion between adjacent vertebra, resisting compression along the support axis of the spinal column, but permitting limited movement between the vertebra to provide the characteristic flexibility of the healthy spine. Injury, disease or other degenerative disorders may cause one or more intervertebral discs to shrink, collapse, deteriorate or become displaced, herniated, or otherwise damaged. This can lead to compression of adjacent nerve root(s) or the spinal cord causing chronic and often disabling pain, and in advanced circumstances, irreversible paralysis of upper and/or lower limbs.

20 25

A number of devices and methods have been suggested for the replacement of damaged or dislocated intervertebral discs. One common approach is to permanently stabilize or "fuse" the adjacent vertebra to maintain the proper intervertebral spacing and eliminate relative movement between the vertebra. Various methods of vertebral stabilization have been developed, for example, autogenous grafts of dowel-shaped sections of bone have been implanted between the vertebra to cause bone growth across the intervertebral space, thereby

30

with tissue ingrowth into porous surfaces. These mechanisms of attachment, however, may lack the degree and strength of fixation desired. Moreover, several such devices have used attachment flanges which extend beyond the surfaces of the vertebra to which the device is attached. This has been found undesirable, as the extending flanges may interfere with or injure adjacent tissue; for example, it has been reported that flanges extending into immediately adjacent delicate esophageal areas may interfere with swallowing and speech, or cause perforation and potentially fatal infection. An additional drawback to the use of screw and pin connections is the potential for such connectors to dislodge and cause injury. Examples of such prosthetic implants are disclosed in the following: U.S. Patent No. 4,759, 769, to *Hedman et al.*, U.S. Patent No. 4,946,378, to *Hirayama et al.*, U.S. Patent No. 4,997,432, to *Keller*, U.S. Patent No. 5,002,576, to *Fuhrmann et al.*, U.S. Patent No. 5,236,460, to *Barber*, U.S. Patent No. 5,258,031, to *Salib et al.*, U.S. Patent No. 5,306,308, to *Gross, et al.*, U.S. Patent No. 5,401,269, to *Buttner-Janz, et al.*, U.S. Patent No. 5,425,773, to *Boyd, et al.* and U.S. Patent No. 5,782,832, to *Larsen, et al.*

Thus, it can be seen that a need yet exists for a spinal implant effective in permanently maintaining intervertebral spacing to prevent nerve or spinal cord compression, while preserving as much of the natural range of motion between the affected vertebra as possible. A need further exists for such a device which is capable of forming a permanent, strong attachment to the vertebra, yet does not protrude beyond the external surfaces to which it is attached. Still another need exists for a method of replacing a damaged or displaced disc, maintaining intervertebral spacing to prevent nerve and spinal cord compression, while preserving the natural relative motion between the vertebra. It is to the provision of devices and methods meeting these and other needs that the present invention is primarily directed.

Brief Summary of the Invention

Briefly described, in a preferred form, the present invention comprises a spinal implant including a first element having first connection means for engaging a first vertebra. The first connection means includes a first fusion chamber having at least one opening therein for facilitating bone ingrowth into the first fusion chamber to fuse the first element to the first vertebra. The implant also includes a second element having second connection means for engaging a second vertebra. The second connection means includes a second fusion chamber having at least one opening therein for facilitating bone ingrowth into the second fusion chamber to fuse the second element to the second vertebra. The implant also includes internal articulation means, coupling the first element to the second element, for allowing relative movement between

the first element and the second element. As used herein, the term "internal articulation means," refers to a means for facilitating relative motion between components of the implant, rather than between the implant and an external structure such as adjacent bone or other tissue.

In specific embodiments of the subject invention, the first and second elements may have
5 either hemi-cylindrical or hemi-elliptical shaped outer surfaces. The first and second elements each having an outer wall perforated with one or more openings provided therein to allow bone ingrowth into the fusion chambers, and having abutting joint surfaces forming the internal articulation means. In a further preferred embodiment, the joint surfaces are formed as engaging concave and convex surfaces to create a ball-and-socket type joint (or rocker and channel, or
10 other such joint), which allows relative pivotal motion between the vertebra, but resists compression there between.

The first and second elements can join to form a single element which can be implanted using methods similar to those followed in the implantation of previously known non-articulating vertebral fusion implants. Temporary stabilizing means can be provided for rigidly coupling the
15 first and second elements by interposition of bioreabsorbable elements to permit implantation and enable bone ingrowth into the fusion chambers and fusion of the first and second elements to adjacent bone during an initial stabilization period, after which said temporary means biodegrades permitting articulation between the first and second elements.

The present invention can be further described as comprising a spinal implant having
20 a first articulation surface, a second articulation surface engaging at least a portion of the first articulation surface along a support axis generally parallel to the spinal column, first connection means for connecting the first articulation surface to a first vertebra, and second connection means for connecting the second articulation surface to a second vertebra. The first and second articulation surfaces resist axial compression between the first and second elements in the
25 direction of the support axis, but allows relative pivotal motion between the first and second elements. At least one, and preferably both, of the first connection means and the second connection means comprise a fusion chamber having at least one opening therein for facilitating bone ingrowth, thereby permanently and securely affixing the implant in place.

In another preferred form, the present invention comprises a method of maintaining an
30 intervertebral space between a first vertebra and a second vertebra. The method includes the steps of removing a section of the first vertebra to form a cavity therein, mounting a first element of a spinal implant within the cavity formed in the first vertebra, and connecting a second element of the spinal implant to the second vertebra. The first element includes a first articulation surface and a first fusion chamber having at least one opening therein for facilitating

bone ingrowth from the first vertebra. The second element includes a second articulation surface, wherein the first and second articulation surfaces adjoin to form a joint allowing relative pivotal movement between the first and second elements but preventing relative compression between the first and second elements. In a further preferred embodiment, the method may also
5 include the removal of a section of the second vertebra to form a cavity for receiving the second element. The second element may also include a second fusion chamber for facilitating bone ingrowth from the second vertebra. Bone fragments formed by the removal of vertebral sections to accommodate implantation or bone growth stimulating compounds or devices may be inserted into the fusion chamber(s) to enhance bone ingrowth.

10 These and other objects, features and advantages of the present invention, will be more readily understood with reference to the following detailed description, read in conjunction with the accompanying figures. All patents, patent applications and publications referred to or cited herein, or from which a claim for benefit of priority has been made, are incorporated by reference in their entirety to the extent they are not inconsistent with the explicit teachings of this
15 specification.

Brief Description of the Figures

Figures 1a & 1b shows a perspective view of a spinal implant according to one cylindrical form of the present invention.

20 Figure 2 shows a cross-sectional side view of the spinal implant of Figure 1.

Figure 3 shows a cross-sectional end view of the spinal implant of Figure 1.

Figure 4a is an end view of a spinal implant *in situ* according to the cylindrical form of the present invention.

25 Figure 4b is a side view of a spinal implant *in-situ* according to the cylindrical form of the present invention.

Figure 5 is a cross-sectional end view of another embodiment of the present invention showing an interposed bowl-shaped cap providing impact resistance and wear resistance.

Figure 6a shows a cross-sectional end view of an elliptically-shaped spinal implant of the subject invention.

30 Figure 6b shows a cross-sectional end view of an alternative elliptically-shaped spinal implant of the subject invention.

Figure 7 shows a cross-sectional side view of the tapered spinal implant.

Figure 8 shows a cross-sectional end view of a spinal implant with a rocker and channel articulating means.

Figure 9 shows a cross-sectional end view of a spinal implant with a hour-glass shaped rocker and a hour-glass shaped channel articulating means.

Figures 10a & 10b show a perspective view of a spinal implant with a rocker and channel articulating means.

5 Figures 11a & 11b show a perspective view of a spinal implant with a rocker and alternative hour-glass channel articulating means.

Figure 12 is an end view of a spinal implant *in-situ* according to the elliptical form of the present invention.

10 Figure 13 is a side view of a spinal implant *in-situ* according to the tapered form of the present invention.

Figure 14a shows a side view of surgical instrument for cutting an elliptical section in between spinal vertebra.

Figure 14b shows a bottom view of surgical instrument for cutting an elliptical section in between spinal vertebra.

15 Figures 15a & 15b show a perspective view of a spinal implant with an alternative diamond shaped channel and corresponding diamond shaped rocker articulating means.

Figure 16 shows a perspective view of a spinal motion segment displaying the Cartesian x, y, and z axes.

20 Figure 17 shows a spinal motion segment comprising two adjacent vertebral bodies and an interposed intervertebral disc rotating about an instantaneous axis.

Figures 18a-18c show an instantaneous axis of rotation below the level of the intervertebral disc of a spinal motion segment in extension/flexion (E, F), right tilt/left tilt (R,L), and right rotation/left rotation (R,L) for various planes.

25 Figures 19a-19c show cervical spinal motion segments in flexion, neutral and extension.

Detailed Disclosure of the Invention

Referring now in detail to the figures, wherein like reference numbers represent like parts throughout, preferred forms of the present invention will now be described. As seen in Figures 1-3, one embodiment of the present invention comprises a spinal implant 10, generally
30 comprising a first element 20 and a second element 22. The first element 20 is coupled to the second element 22 by an internal articulation means 24 for allowing relative pivotal movement between the first and second elements.

Figures 4A and 4B show the spinal implant 10 of the present invention installed *in situ*, between a first vertebra 12 and a second vertebra 14. The implant 10 is shown implanted into

an anterior aspect of the vertebral body, between the fifth cervical and sixth cervical vertebra. The device and method of the present invention, however, are applicable to anterior, lateral, and posterior approaches to the vertebra.

As seen best in Figs. 2-3, the first element 20 of the implant 10 comprises first
5 connection means, in the form of a first fusion chamber 30, for engaging the first vertebra 12. At least one opening 32 is formed in the first fusion chamber 30, to facilitate bone growth into, through and around the first fusion chamber 30 from the first vertebra 12, to fuse the first
10 element to the first vertebra 12. Preferably, a plurality of openings 32 are provided to further promote bone ingrowth. Fusion by bone ingrowth has been found to provide a more permanent, rigid connection between the implant 10 and the skeletal structure, than provided by other known
connection means.

The second element 22 of the implant 10 comprises a second connection means for
engaging the second vertebra 14. The second connection means preferably comprises a second
15 fusion chamber 34, substantially similar in construction to the above-described first fusion chamber 30, and comprising at least one opening 36 formed therein for facilitating bone growth into, through, and around the second fusion chamber 34 from the second vertebra 14. Alternatively, the second connection means can comprise an adhesive connection, screw
20 connection, pin connection, or any other effective alternative connection means. However, the provision of a second fusion chamber 34 is preferred, as it provides a more permanent and secure coupling than other known attachment means. Although the first element 20 and first vertebra
12 are depicted in the figures as above the second element 22 and second vertebra 14, it will be understood that the present invention equally comprehends the reverse configuration wherein the first element, as described herein, is attached to a first vertebra lower on the spinal column
25 than the second vertebra to which is attached the second element. The first and second elements can be fabricated from biocompatible materials including, without limitation, titanium, surgical alloys, stainless steel, chrome-molybdenum alloy, cobalt chromium alloy, zirconium oxide ceramic, nonabsorbable polymers and other anticipated biocompatible metallic or polymeric materials.

Referring now to Figs. 2-3, the articulation means 24 of the present invention preferably
30 comprises a first articulation surface 40 provided on the first element 20, and an abutting second articulation surface 42 provided on the second element 22. The first and second articulation surfaces 40, 42 are preferably fabricated from or coated with low-friction, wear and impact-resistant, biocompatible materials, such as, for example, titanium, stainless steel, surgical alloys, chrome-molybdenum alloys, cobalt chromium alloy, zirconium oxide ceramic, non-absorbable

polymers and other biocompatible metallic or polymeric materials. The articulation means 24 resists axial compression between the first and second elements 20, 22, but allows relative pivotal movement there between. Thus, when implanted, as shown in Figure 4, the articulation means 24 resists axial compression between first and second vertebra 12, 14 along a support axis 44 extending generally along the spinal column, as shown, for example, in Figure 4, but permits pivotal movement between vertebra. The term "pivotal," is intended to comprehend either or both of a rotational or twisting motion about the support axis 44 (for example, rotation between cervical vertebra by turning the head to the right or left), and/or a tilting motion angularly inclined in any direction relative to the support axis 44 (for example, nodding the head forward or backward and/or tilting the head downward to the right or left).

In a preferred embodiment, axial compression, as well as lateral translation normal to the support axis 44, is resisted between the first and second vertebra 12, 14, by providing the first internal articulation surface 40 with a void, such as a concave surface 46, which receives a protuberance, such as a convex surface 48, projecting from the second internal articulation surface 42. This "ball-and-socket" arrangement allows relative rotation about the support axis 44 between the first and second vertebra 12, 14. The articulation means 24 can be provided with one or more stops to limit the range of rotational movement allowed.

In addition to the "ball-and socket" arrangement for the articulating means 24, other configurations are possible which more closely follow the bio-mechanical motions of the first and second vertebra. The instantaneous motion of the first and second vertebra can be defined using the instantaneous axis of rotation. At every instant for a rigid body in plane motion, there is a line in the body or a hypothetical extension of this line that does not move. The instantaneous axis of rotation is this line. Plane motion is fully defined by the position of the instantaneous axis of rotation and the magnitude of the rotation about it. The resultant actions of the elementary movements between pairs of adjacent vertebra are the movements of flexion and extension. As shown in Figure 17, the displacement of flexion-extension can be described as a circular movement about a transverse axis, where the axis is not situated at the level of the nucleus pulposus but lies below, in the body of the lower vertebra. The cartilage-lined articular facets produce an articular interface inscribed on the arc of a circle with the same center. The superior surface of the disc is also inscribed on an arc with the same center. The movement of the upper vertebra thus describes an arc with arcuate sliding of the articular facets and pendulous displacement of the disc about the same geometric center, known as the instantaneous axis of rotation. The instantaneous motion of a rigid body in three-dimensional space can be described as the resultant of the three rotations about the x, y and z axes, as shown in Figure 16. As shown

in Figures 18a-18c, the center varies during a given movement and describes an area comprising the instantaneous axis of rotation.

The location of the instantaneous axis of rotation may vary according to the region of the spine, for example, in the case of the C2-C3 articulation in the cervical spine, the instantaneous axis of rotation is geometrically lower than other centers in the cervical spine and is found in the body of C4. Below the C2-C3 intervertebral joint, the instantaneous axis of rotation of each cervical intervertebral articulation lies in the inferior part of the lower vertebra. In the thoracic and lumbar regions, the instantaneous axis of rotation is located in the central part of the superior surface of the lower vertebra. One consequence of this lower position of the instantaneous axis of rotation in flexion /extension is the anterior sliding or anterolisthesis of one superior or upper vertebra in the subjacent vertebra during extension.

This unexpected sliding movement is termed paradoxical motion. In paradoxical motion a functional spinal unit rotates in extension when the overall motion of the segment is in flexion. As shown in Figure 19a, the functional spinal unit is in flexion, yet an unexpected (-x axis) rotation of the C5 vertebra occurs, a movement that would be expected if the functional spinal unit were in extension. The converse also occurs with extension. As shown in Figure 19c, the functional spinal unit is in extension and a posterior (-z axis) translation is expected, yet the C5 vertebra displays an anterior (+z axis) translation. These paradoxical motions are described in the sagittal plane; they could also occur in the frontal and horizontal planes as well. An objective of the subject invention is a spinal implant which permits a first vertebra and second vertebra to articulate about an instantaneous axis of rotation and display paradoxical motion, where the articulation of the first vertebra and second vertebra is substantially similar to the physiological motion of a substantially identical pair of adjacent vertebrae interacting with a natural intervertebral disc.

An example of a spinal implant with an articulating means which permits the first vertebra and second vertebra to articulate about an instantaneous axis of rotation and display paradoxical motion is shown in Figures 8, 10a and 10b, where the articulating means comprises a rocker 100 and channel 101. The second articulation surface 42 can comprise a substantially U-shaped channel 101 extending along the length of the second element 22. The first articulation surface 40 comprises a correspondingly shaped rocker 100 which can be, for example, hemi-elliptical in shape along the length of the first element 20. The rocker 100 and channel 101 articulating means simulate the physiological spinal articulating conditions of a vertebral disc during flexion and extension by allowing the first and second vertebra to rotate about an instantaneous axis, as shown in Figure 17, and display paradoxical motion.

Additionally, by increasing the number of ranges of motion, the spinal implant can rotate about an instantaneous axis and display paradoxical motion in the frontal and horizontal planes as well. Furthermore, by allowing the first and second vertebra to rotate about an instantaneous axis, the rocker 100 and channel 101 articulating means 24 can decrease the progressive degeneration of adjacent intervertebral discs by decreasing the nonphysiological bio-mechanical stresses and reducing the increase in intradiscal pressures normally associated with vertebral fusion.

In an alternative to this embodiment, as shown in Figure 9, a second range of motion can be added to the articulating means 24 by modifying the shape of the channel 102. The modified channel 102 can be, for example, substantially hour-glass in shape through the depth of the channel 102. The channel width at the channel's base 103 and mouth 104 are greater than the channel width at the channel's midpoint 105. The hour-glass shaped channel 102 permits a tilting motion along two perpendicular linear planes.

In a second alternative to this embodiment, as shown in Figures 11a and 11b, an alternative second range of motion can be added to the articulating means 24 by modifying the shape of the channel 101. The modified channel 106 can be, for example, substantially hour-glass in shape through the length of the second element 22. The channel width at the channel's longitudinal midpoint 107 is less than the channel width at the channel's leading end 108 and tail end 109. Those skilled in the art, having the benefit of the instant disclosure, will appreciate that the "hour-glass" shape as described herein includes various curves or straight edges so long as the width at, or near, the end points of the channel (or the top and bottom of the channel) is wider than the width at some point between the end points. The hour-glass shaped channel 106 permits two ranges of motion, a tilting motion and a pivoting motion, about the central axis. These motions may be desirable for some patients.

In a third alternative to this embodiment, as shown in Figures 15a and 15b, an alternative second range of motion can be added to the articulating means 24 by modifying the shape of the channel 101. The modified channel 110 can be, for example, substantially diamond in shape through the length of the second element 22. The channel width at the channel's longitudinal midpoint 111 is greater than the channel width at the channel's leading end 112 and tail end 113. Additionally, the first articulation surface 40 comprises a correspondingly-shaped rocker 114 which can be, for example, diamond in shape along the length of the first element 20. Those skilled in the art, having the benefit of the instant disclosure, will appreciate that the "diamond" shape as described herein includes various curves or straight edges so long as the width at some point between the end points of the channel (or the top and bottom of the channel) is wider than the width at, or near, the end points. The diamond shaped channel 110 permits three ranges of

respective first and second articulating surfaces 40, 42 adjacent and engaging one another, as described above. The first element 20 preferably further comprises a first radiused outer wall 60. The one or more openings 32 for facilitating bone ingrowth are provided in this first radiused outer wall 60, and communicate with a first fusion chamber 62 formed between the first radiused outer wall 60 and the first articulating surface 40. Similarly, the second element 22 preferably comprises a second radiused outer wall 70, defining one or more openings 36 for facilitating bone ingrowth. The openings 36 communicate with a second fusion chamber 72 formed between the second radiused outer wall 70 and the second articulating surface 34. The first and second radiused outer walls 60, 70 can be provided with threads 80 to facilitate advancing the implant 10 into the intervertebral space during implantation and to help secure the implant 10 in position once implanted. The threads 80 on each of the first and second radiused outer walls 60, 70 are preferably aligned to form continuous threads when the first and second elements 20, 22 are engaged. In some instances, it may be desirable to provide self-tapping threads 80, and/or to configure the threads 80 to direct bone fragments generated by implantation into the openings 32, as taught by U.S. Patent No. 5,489,308 to *Kuslich, et al.* In other less preferred embodiments, the threads 80 can be replaced with a contoured outer surface comprising smooth, splined, flanged, spiked or beaded surface features. The implant 10 can further comprise one or more support flanges 85 in the first and/or second elements 20, 22, for additional strength.

In a second embodiment as shown best by Figures 6a, 6b and 12, the first and second elements 20, 22 of the implant 10 of the present invention preferably comprise hemi-elliptical outer walls 97, 99 adjoining to form an elliptical body. When in their assembled configuration, the first element 20 and the second element 22 abut one another with their respective first and second articulating surfaces 40, 42 adjacent and engaging one another, as described above. The first element 20 preferably further comprises a first radiused outer wall 97. The one or more openings 32 for facilitating bone ingrowth are provided in this first radiused outer wall 97, and communicate with a first fusion chamber 62 formed between the first radiused outer wall 97 and the first articulating surface 40. Similarly, the second element 22 preferably comprises a second radiused outer wall 99, defining one or more openings 36 for facilitating bone ingrowth. The openings 36 communicate with a second fusion chamber 72 formed between the second radiused outer wall 99 and the second articulating surface 42. In alternative embodiments the contoured outer surfaces of the first and second elements 20, 22 can comprise smooth, splined, flanged, spiked or beaded surface features to secure the element in position once implanted. The implant

10 can further comprise one or more support flanges 85 in the first and/or second elements 20, 22, for additional strength.

In another embodiment, as shown in Figures 7 and 13, the element 10 may be tapered along the horizontal axis. The tailing end 92 has a vertical radius greater than the vertical radius of the leading end 93. The tapered shape decreases the amount of material required to be removed and increases the ease of insertion of the implant 10 in between the first and second vertebra.

In still further embodiments, the spinal implant 10 may have a first and second element for affixing the spinal implant 10 to a first and second vertebra in the shape of a rectangular plate or any of the affixing means as disclosed in the following: U.S. Patent No. 4,759, 769, to Hedman, *et al.*, U.S. Patent No. 4,946,378, to Hirayama, *et al.*, U.S. Patent No. 4,997,432, to Keller, U.S. Patent No. 5,002,576, to Fuhrmann, *et al.*, U.S. Patent No. 5,236,460, to Barber, U.S. Patent No. 5,258,031, to Salib, *et al.*, U.S. Patent No. 5,306,308, to Gross, *et al.*, U.S. Patent No. 5,401,269, to Buttner-Janz, *et al.*, U.S. Patent No. 5,425,773, to Boyd, *et al.*, and U.S. Patent No. 5,782,832, to Larsen, *et al.*

In a further preferred embodiment. As shown in Figure 2-3, the present invention may further comprise the provision of one or more stabilizing means for temporarily rigidly coupling the first element 20 to the second element 22 to prevent relative movement there between, for example, it is preferred that the first and second elements 20, 22 be held rigidly in place during installation of the implant 10 into the intervertebral space. In addition, the first and second elements 20, 22 should remain rigidly coupled for a sufficient length of time after implantation to permit sufficient bone ingrowth into the fusion chambers to prevent relative motion between the implant 10 and the vertebra 12, 14 during normal activities of the patient. Typically, approximately eight to twenty weeks of bone ingrowth will be sufficient, before the first and second elements 20, 22 are uncoupled and permitted to articulate relative to one another. This temporary stabilization of the first and second elements is accomplished by the present invention, without the requirement of a second surgical procedure, through the use of medium-term stabilizing means formed from bioreabsorbable material. Examples of bioreabsorbable materials include polyglycolate polymers or analogues, lactides, polydioxanone, polyglyconate, lactide/glycolide copolymers. By appropriate selection of the material(s) of construction, the length of time required to biodegrade the stabilizing means can be effectively controlled. After the stabilizing means are dissolved and absorbed by the body, the first and second elements of the implant 10 are uncoupled, allowing articulation. In one example embodiment, depicted in Figure 3, the stabilizing means can comprise one or more biodegradable shims 82 wedged

between the first element 20 and the second element 22, to prevent relative motion there between. In another example embodiment, the first and second elements 20, 22 are placed in their coupled configuration, as shown in Figs. 2-3, with the spaces between the articulating surfaces 40, 42, then being injected or filled with a biodegradable polymer, which provides the medium term temporary stabilizing means to couple the elements in position. Care will be taken to avoid filling the fusion chambers 30, 34 and the openings 32, 36 to the fusion chambers with the polymer, which could inhibit bone ingrowth. The threads 80 will also remain exposed to assist in implantation of the device. In another example embodiment, depicted in Figure 2, the stabilizing means comprise a removable and/or bioreabsorbable endcap 90, which releasably engages the tailing end 92 of the implant 10 to couple the first and second elements 20, 22. The endcap can comprise one or more clips 94 for engaging the implant 10, and one or more keyways 96 for engaging a wrench, driver or other actuation device used to advance the implant 10 into the intervertebral space. A second removable and/or absorbable endcap can be installed on the leading end 93 of the implant 10. The endcaps may additionally function to retain the bone fragments within the chambers 62, 72 of the fusion chambers 30, 34, as will be described in greater detail below, until sufficient bone ingrowth and fusion has occurred.

Another embodiment of the present invention is depicted by Figure 5, which shows an implant 10, generally comprising first and second elements 20, 22, substantially as described above, and further comprising an intermediate articulation element, which in the depicted embodiment comprises a generally hemispherical bowl-shaped cap 90 interposed between the concave surface 46 of the first element 20 and the convex surface 48 of the second element 22. The cap 90 is preferably fabricated from a wear-resistant, low friction material of construction, which may be somewhat resilient to absorb impact loading. The provision of the cap 90 allows articulation at the interface between the top surface of the cap and the concave surface 46 of the first element 20, and between the bottom surface of the cap and the convex surface 48 of the second element 22, resulting in a bipolar articulation. This arrangement reduces frictional wear on the articulation surfaces by distributing wear over two articulation interfaces. The engagement of the concave lower surface of the cap 90 with the convex surface 48 of the second element 22, and the engagement of the convex upper surface of the cap 90 with the concave surface 46 of the first element 20, prevents the cap 90 from becoming dislodged when the implant 10 is installed.

The present invention further comprises a method of maintaining a desired intervertebral space between a first vertebra 12 and a second vertebra 14. The method preferably comprises removing a section of the first vertebra to form a cavity therein, mounting a first element of an

articulating spinal implant into the cavity, and connecting a second element of the implant to the second vertebra. The articulating spinal implant used to carry out this method is preferably substantially similar to the example embodiment described above, having first and second internal articulation surfaces which adjoin to form a joint allowing relative pivotal movement
5 between the first and second elements, but preventing relative axial compression there between. At least one of the elements preferably further comprises a fusion chamber, including a chamber and at least one opening communicating with the chamber, for facilitating bone ingrowth into, through, and around the fusion chamber from the respective vertebra. In a preferred form, the method of the present invention comprises attachments of both the first and second elements of
10 the implant to the respective vertebra using fusion chambers for bone ingrowth. In this embodiment, a section of the second vertebra is preferably removed to form a cavity therein for receiving the second element of the implant. The method of the present invention can further comprise the insertion of bone fragments, which may be the fragments formed in the above-described removal of vertebral sections, into the fusion chamber(s) of the implant. The presence
15 of these bone fragments has been shown to stimulate and enhance bone ingrowth into the fusion chamber. In another embodiment, the method of the present invention anticipates the application of means for stimulating bone growth into, through, and/or around the fusion chamber(s). The means for stimulating bone growth can comprise, for example, electrical or magnetic bone growth stimulators, bone morphogenetic protein (BMP), hydroxyl apatite compounds, demineralized bone compound, and/or other bone growth stimulating devices or compounds.
20 It is also anticipated that the introduction of a cyanoacrylate material, commonly referred to as surgical glue, onto the outer surface of the fusion chamber(s) may be used to fix the implant in optimal position awaiting bone ingrowth.

Implantation of the articulating spinal implant, according to the present invention, may
25 be carried out in a manner generally similar to previously-known methods for the implantation of non-articulating, rigid-fusion implants, with exceptions as set out herein, for example, the method of the present invention may utilize standard surgical approaches to the spine from either an anterior approach for the cervical and thoracic spinal segments, or from an anterior or posterior lateral approach to the lumbar spinal segments. The removal of vertebral sections may
30 be accomplished by drilling or chipping a generally circular bore having a diameter and depth adapted to generally match the implant to be utilized, bridging the first and second vertebra. Additionally, the circular bore may be tapered with the leading end diameter being smaller than the tail end diameter. The bore is preferably centered over the intervertebral space,

approximately midway between the first and second vertebra. Threads may then be tapped into the bore to facilitate insertion of the implant.

In an alternative method, the removal of vertebral sections may be accomplished by using an unique surgical instrument, as shown in Figures 14a and 14b, for drilling an elliptical
5 bore having a major and minor diameter and depth adapted to generally match the implant to be utilized, bridging the first and second vertebra. Preferably, the surgical instrument is affixed to a drill to provide rotational power to the cutting portion. The cutting portion of the surgical instrument consists of a circular flute drill bit sheathed within cutting blades formed in an elliptical shape. The flute drill bit extends out beyond cutting blades to cut a circular section
10 between the first and second vertebra. As the drill bit cuts into the vertebra, the cutting blades then remove the remaining material to form an elliptical bore having a major and minor diameter and depth adapted to generally match the implant to be utilized, bridging the first and second vertebra.

Alternatively, the implant can be provided with self-tapping threads. The implant is
15 assembled with the first and second articulating surfaces engaged, and the first and second elements of the implant are rigidly coupled by stabilizing means substantially as described above. The stabilized implant is advanced into the bore to the desired depth. Preferably, the implant is advanced until the tailing end 92 is flush or slightly recessed relative to the outer surface of the vertebra, thereby eliminating the possibility that outwardly projecting portions of
20 the implant may interfere with or injure adjacent or regional vascular, neural or visceral structures.

In the lumbar area, where greater load bearing is required, two articulating implants can be placed in parallel positions with the lengthwise axis of each adjacent one to the other, in a generally parallel arrangement, allowing flexion/extension movement alone. This arrangement
25 will typically require removal of vertebral material to form two openings, or an extended opening to accommodate both implants. Alternatively, a single, appropriately sized implant could be placed in the interspace utilizing the transabdominal open surgical approach, the transabdominal laparoscopic approach, or the retroperitoneal open anterior approach allowing pivotal motion around the single point of articulation as described above for use in cervical and thoracic
30 intervertebral disc spaces.

Post-operatively, bone ingrowth will occur, fusing the first and/or second elements of the implant to the respective vertebra. After sufficient passage of time, the stabilizing means is dissolved and absorbed into the body, uncoupling the articulation means to permit relative motion between the first and second elements, thus preserving spinal flexibility and minimizing

References

Van C. Mow and Wilson C. Hayes, Basic Orthopaedic Biomechanics, 2nd Edition, (Lippincott-Raven Publisher) (1997).

- 5 Augustus A. White III and Manohar M. Panjabi, Biomechanics of the Spine, 2nd Edition, (Lippincott-Raven Publisher) (1990).

René Louis, Surgery of the Spine, Surgical Anatomy and Operative Approaches, (Springer-Verlag Berlin Heidelberg New York) (1983)

- 10 Josef Pospiech, M.D., Dietmer Stolke, M.D., Hans J. Wilke, Ph.D., Lutz E. Claes, Ph.D.,
Intradiscal Pressure Recording in the Cervical Spine, Neurosurgery, Vol 44, No. 2, 379
(February 1999).

Claims

1 1. A spinal implant comprising an articulating means interposed between a first vertebra
2 and a second vertebra, wherein said articulating means permits an articulation of said first
3 vertebra and said second vertebra about an instantaneous axis of rotation, whereby said
4 articulation of said first vertebra and said second vertebra is substantially similar to the bio-
5 mechanical motion of a substantially identical pair of adjacent vertebrae interacting with a
6 natural intervertebral disc.

1 2. The spinal implant according to Claim 1, further comprising a first element,
2 comprising a first articulating surface and a first connection means for engaging said first
3 vertebra, a second element comprising a second articulating surface and a second connection
4 means for engaging said second vertebra.

1 3. The spinal implant according to Claim 2, wherein said first articulation surface abuts
2 said second articulation surface to form said articulation means.

1 4. The spinal implant according to Claim 3, wherein said articulation means comprises
2 a channel along a length of said second element and a rocker along a length of said first element,
3 wherein at least a portion of said rocker is engaged within said channel.

1 5. The spinal implant according to Claim 4, wherein said channel along the length of
2 said second element has a width at a top and a bottom of said channel which is greater than a
3 width at some point, between said top and said bottom of said channel.

1 6. The spinal implant according to Claim 4, wherein said channel along the length of
2 said second element has a channel width at a leading end and a tail end which is greater than the
3 channel width at some point between said leading end and said tail end.

1 7. The spinal implant according to Claim 4, wherein said channel along the length of
2 said second element has a channel width at a leading end and a tail end which is less than the
3 channel width at some point between a said leading end and said tail end.

1 8. The spinal implant according to Claim 7, wherein said rocker along the length of said
2 first element has a rocker width at a leading end and a tail end which is less than the rocker width
3 at some point between said leading end and said tail end.

1 9. The spinal implant according to Claim 1, wherein said articulation of said first
2 vertebra and said second vertebra is a rotation about said instantaneous axis of rotation.

1 10. The spinal implant according to Claim 9, wherein said articulation of said first
2 vertebra and said second vertebra is a rotation in the sagittal plane.

1 11. The spinal implant according to Claim 9, wherein said articulation of said first
2 vertebra and said second vertebra is a rotation in the frontal plane.

1 12. The spinal implant according to Claim 9, wherein said articulation of said first
2 vertebra and said second vertebra is a rotation in the horizontal plane.

1 13. The spinal implant according to Claim 9, wherein said articulation of said first
2 vertebra and said second vertebra is a rotation in the sagittal, frontal and horizontal planes.

1 14. The spinal implant according to Claim 1, wherein said articulation of said first
2 vertebra and said second vertebra is a paradoxical motion.

1 15. The spinal implant according to Claim 14, wherein said articulation of said first
2 vertebra and said second vertebra is a paradoxical motion in the sagittal plane.

1 16. The spinal implant according to Claim 14, wherein said articulation of said first
2 vertebra and said second vertebra is a paradoxical motion in the frontal plane.

1 17. The spinal implant according to Claim 14, wherein said articulation of said first
2 vertebra and said second vertebra is a paradoxical motion in the horizontal plane.

1 18. The spinal implant according to Claim 14, wherein said articulation of said first
2 vertebra and said second vertebra is a paradoxical motion in the sagittal, frontal and horizontal
3 planes.

1 19. A method of maintaining an intervertebral space between a first vertebra and a
2 second vertebra, said method comprising the steps of

- 3 (a) removing a section of said first vertebra and said second vertebra to form a
4 cavity therein;
5 (b) mounting a first element of a spinal implant within the cavity formed in the first
6 vertebra, said first element comprising a first articulating surface, and a first
7 connection means for engaging said first vertebra;
8 (c) mounting a second element of said spinal implant within the cavity formed in
9 the second vertebra, said second element comprising a second connection
10 means for engaging the second vertebra, and a second articulation surface,
11 wherein said first and second articulation surfaces adjoin to form an articulating
12 means, wherein said articulating means permits an articulation of said first
13 vertebra and said second vertebra about an instantaneous axis of rotation,
14 whereby said articulation of said first vertebra and said second vertebra is
15 substantially similar to the physiological spinal motion of a substantially
16 identical pair of adjacent vertebrae interacting with a natural intervertebral disc.

1 20. A method of designing an articulating spinal implant, wherein said articulating
2 spinal implant is positioned in an intervertebral space between a first vertebra
3 and a second vertebra, said method comprising the steps of:

- 4 (a) determining a physiological motion of a pair of said first vertebra; and
5 said second vertebra interacting with a natural intervertebral disc,
6 wherein said physiological motion includes a rotation about an
7 instantaneous axis of rotation and a paradoxical motion in a sagittal
8 plane, a frontal plane and a horizontal plane;
9 (b) selecting at least one desired motion, wherein said motion is selected
10 from said physiological motions determined in step (a);
11 (c) creating an articulating means, wherein said articulating means permits
12 an articulation of said desired motion of said first vertebra and said
13 second vertebra; and

- 14 (d) selecting a connection means, wherein said connection means attaches
15 said articulation means to said first vertebra and said second vertebra.

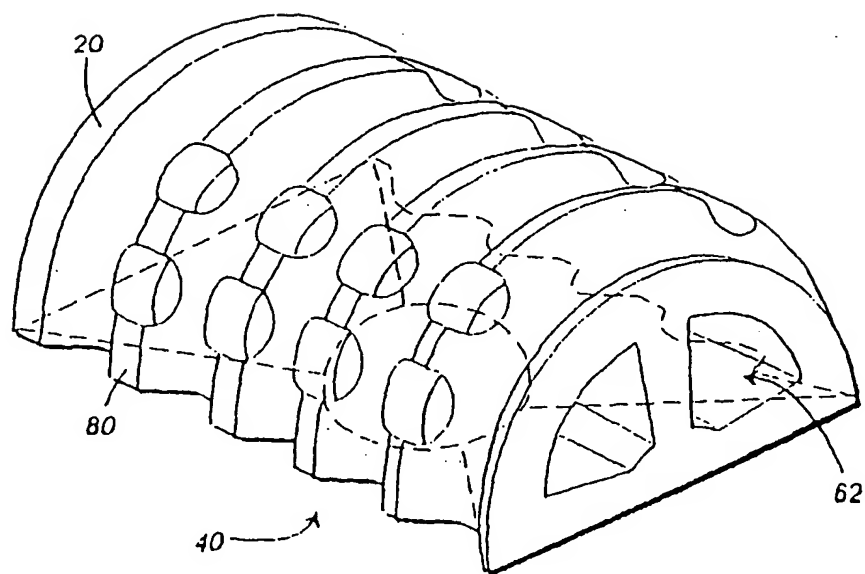


FIG. 1A

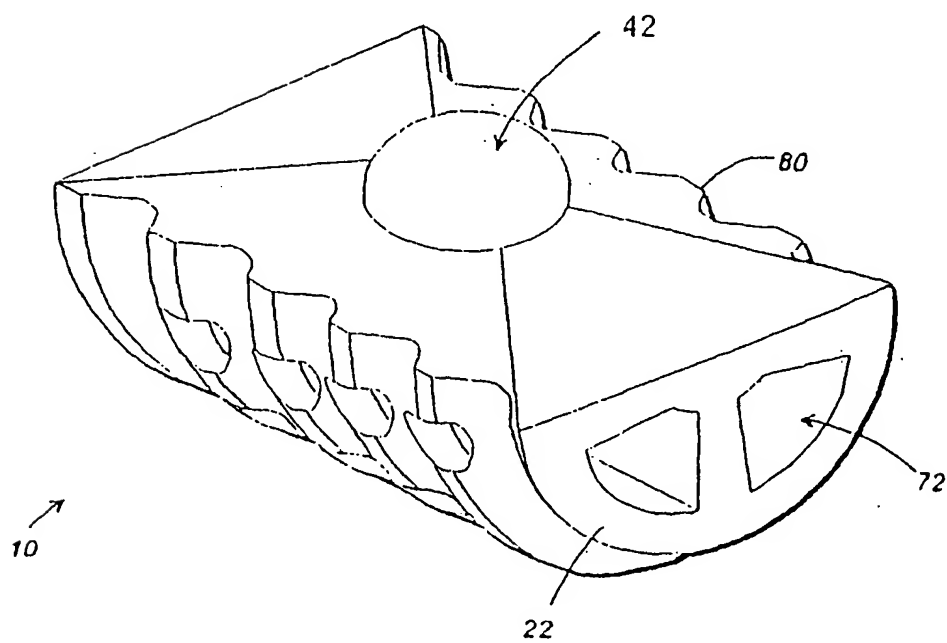


FIG. 1B

2/12

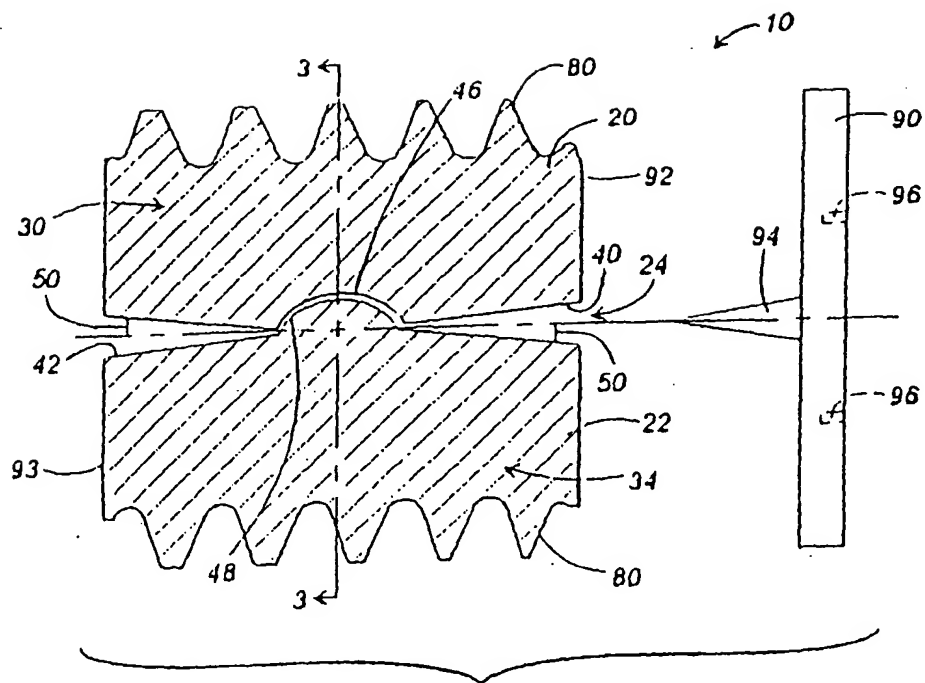


FIG. 2

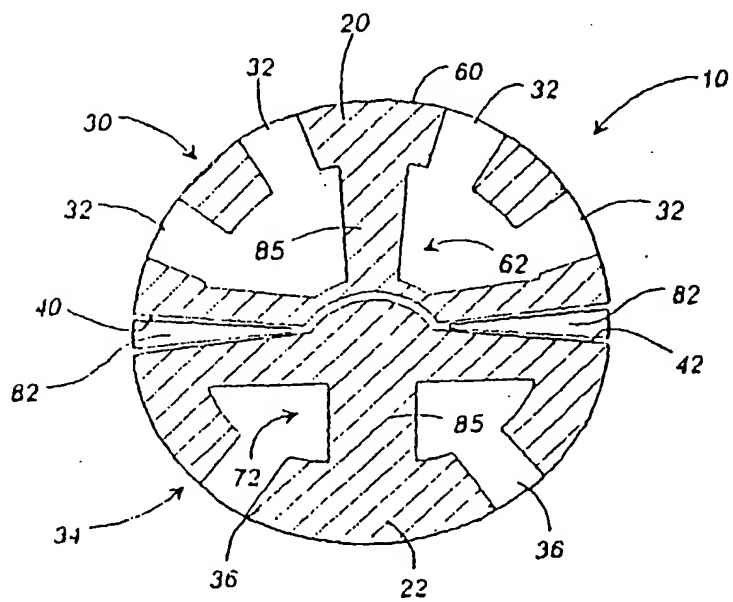


FIG. 3

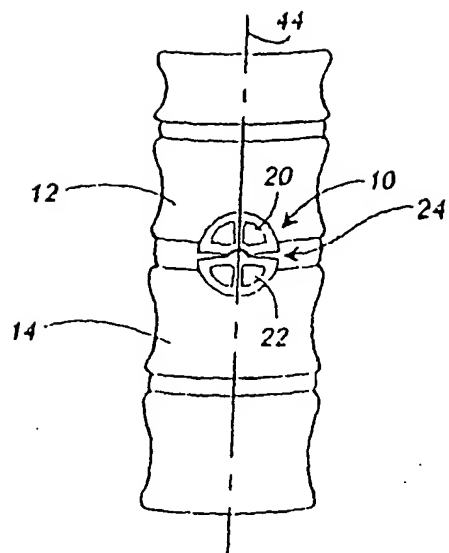


FIG. 4A

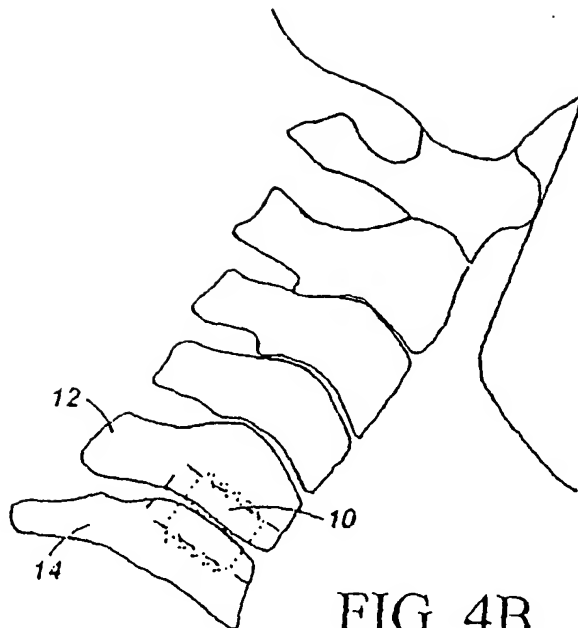


FIG. 4B

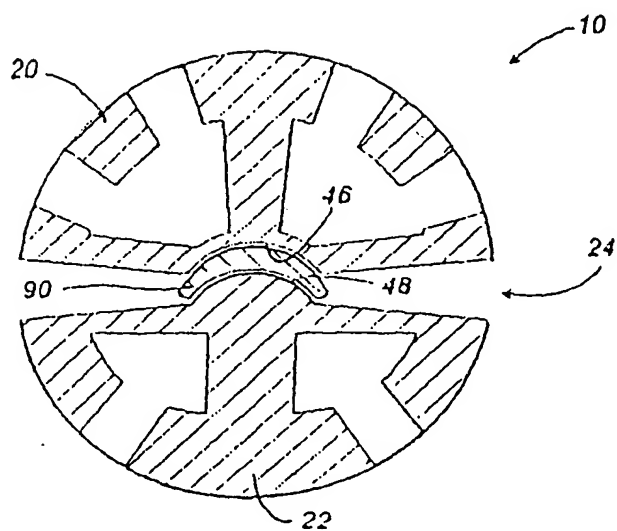


FIG. 5

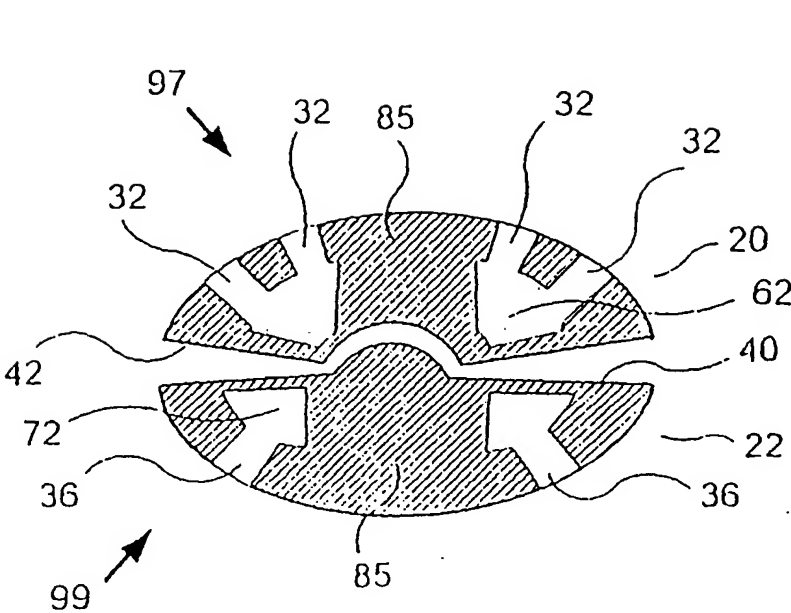


FIG. 6A

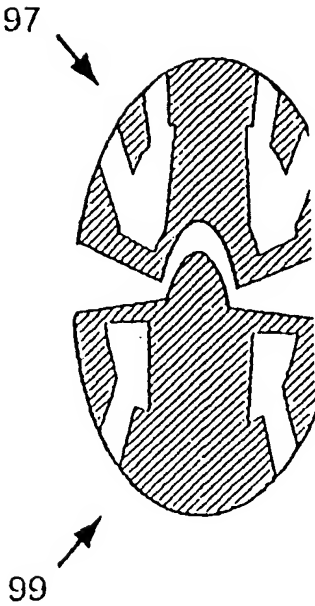


FIG. 6B

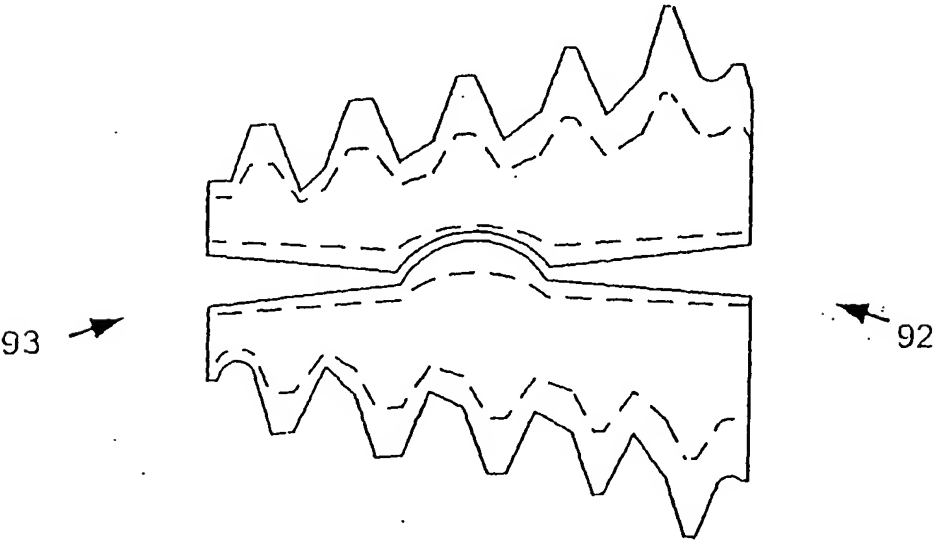


FIG. 7

5/12

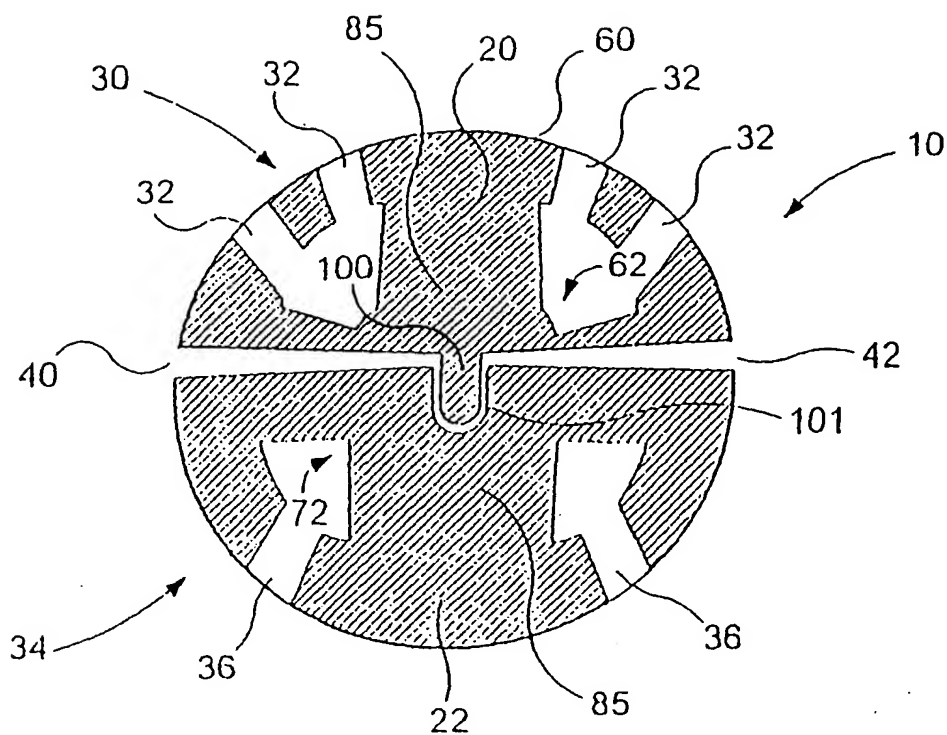


FIG. 8

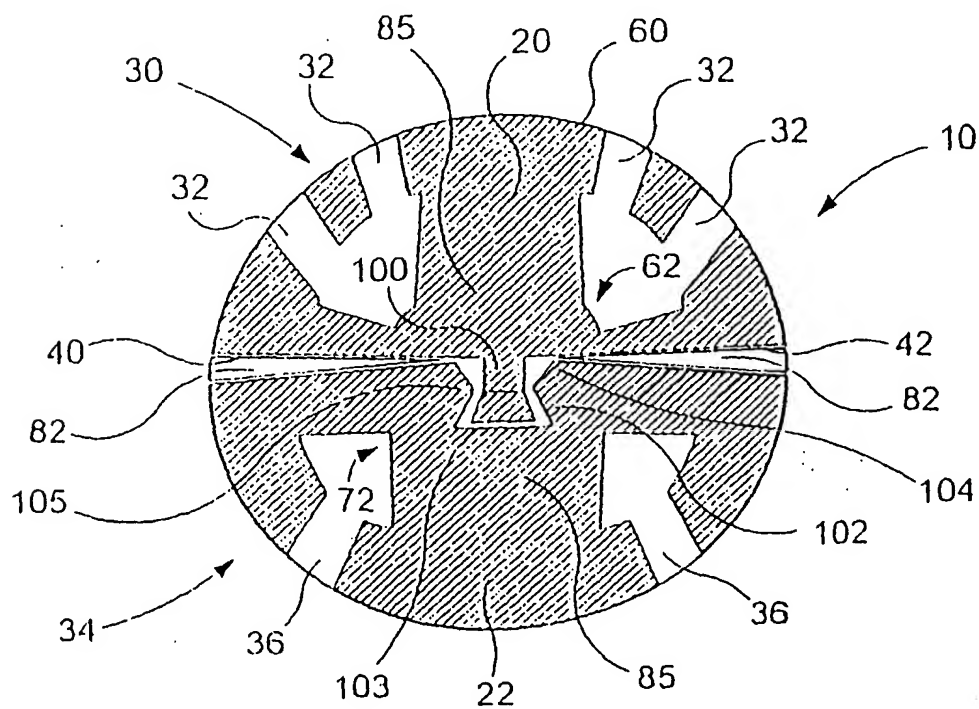


FIG. 9

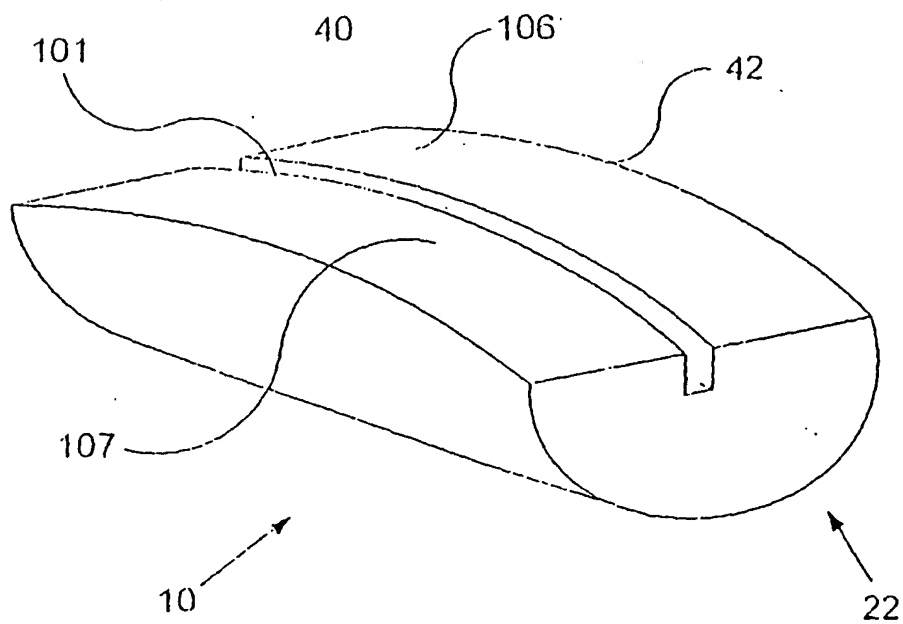
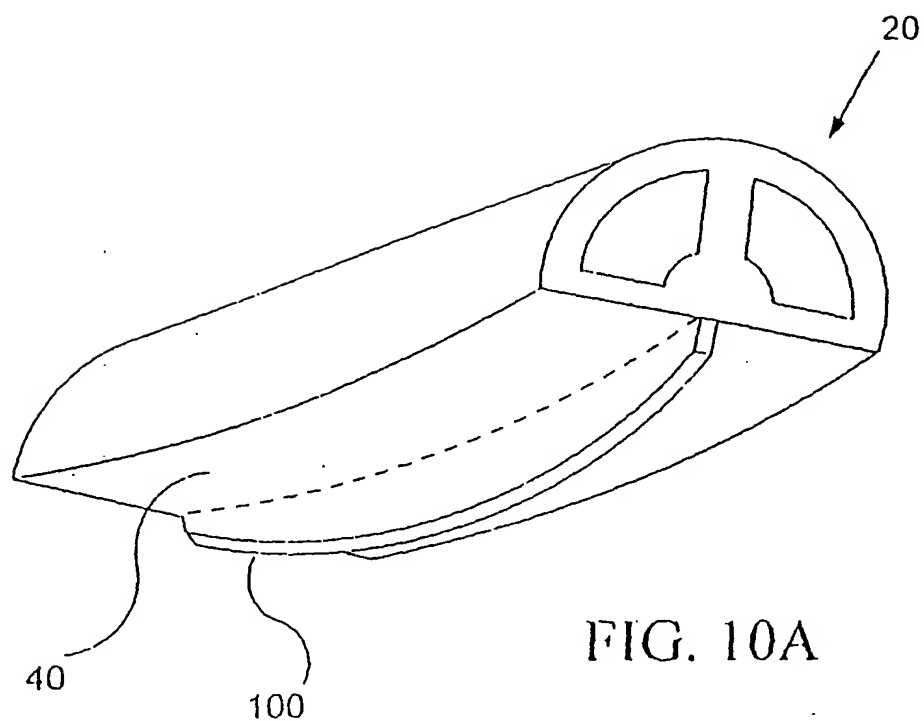
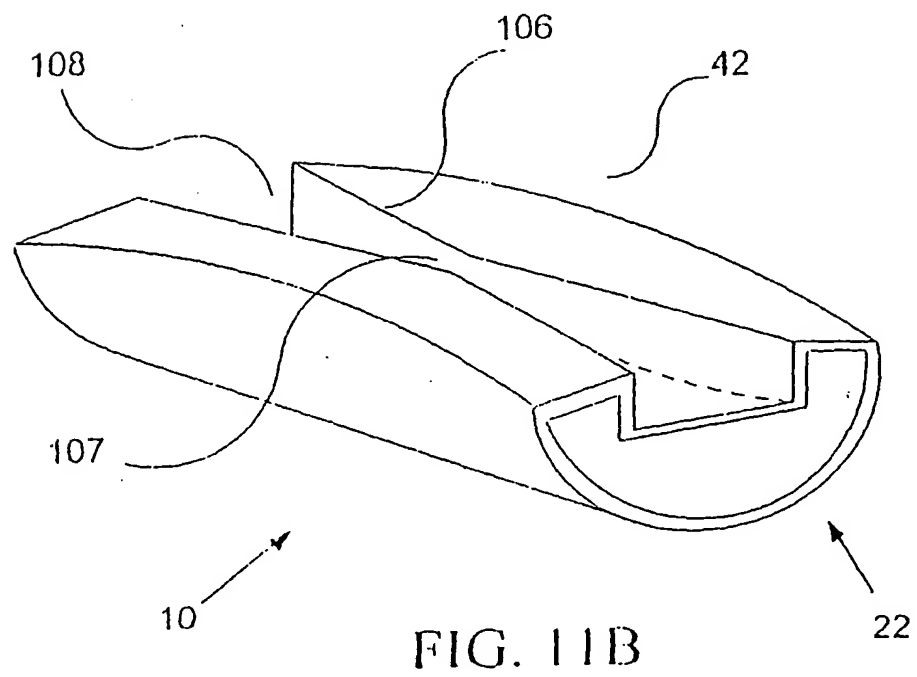
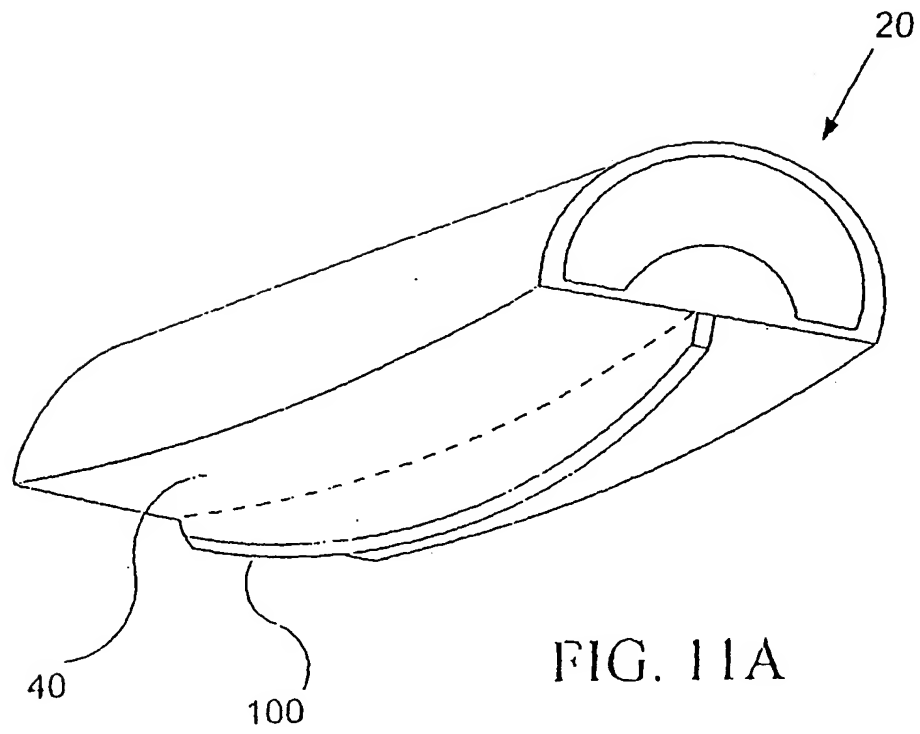


FIG. 10B

7/12



8/12

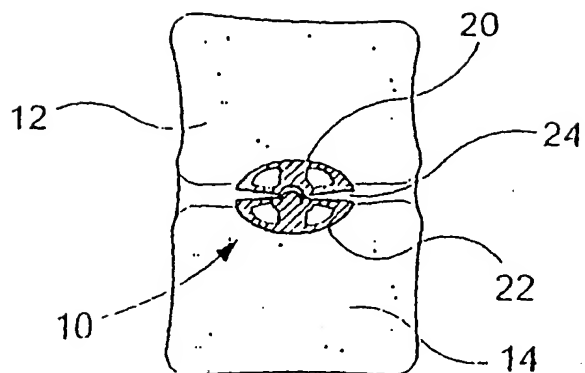


FIG. 12

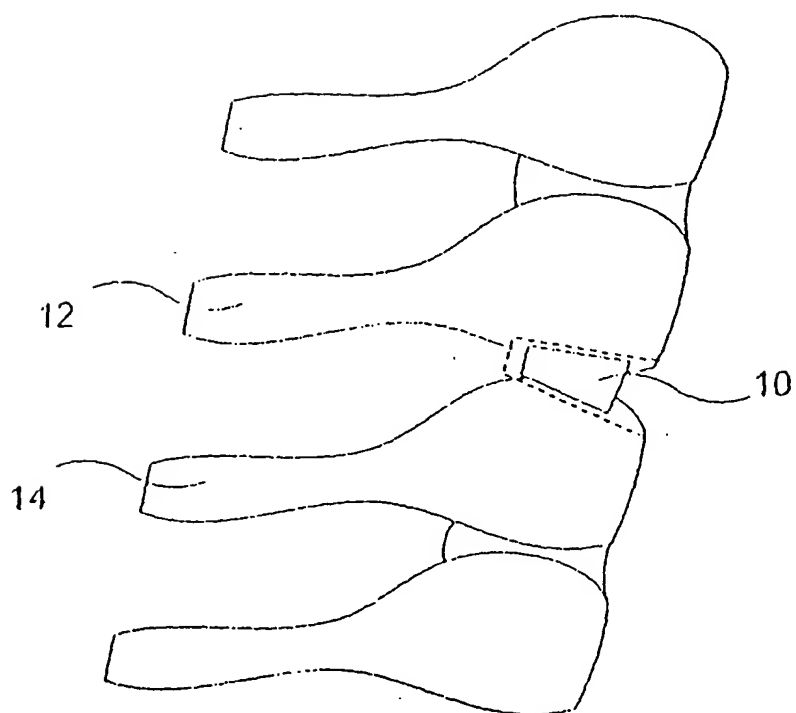


FIG. 13

9/12

FIG. 14A

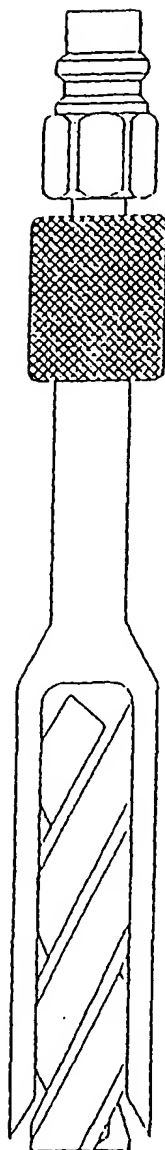


FIG. 14B



10/12

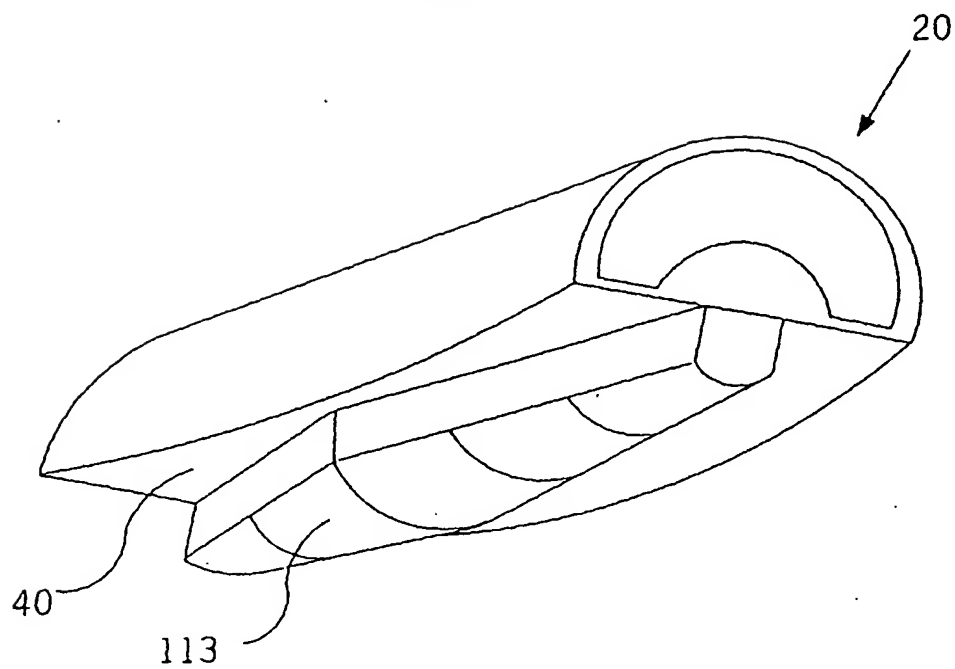


FIG. 15A

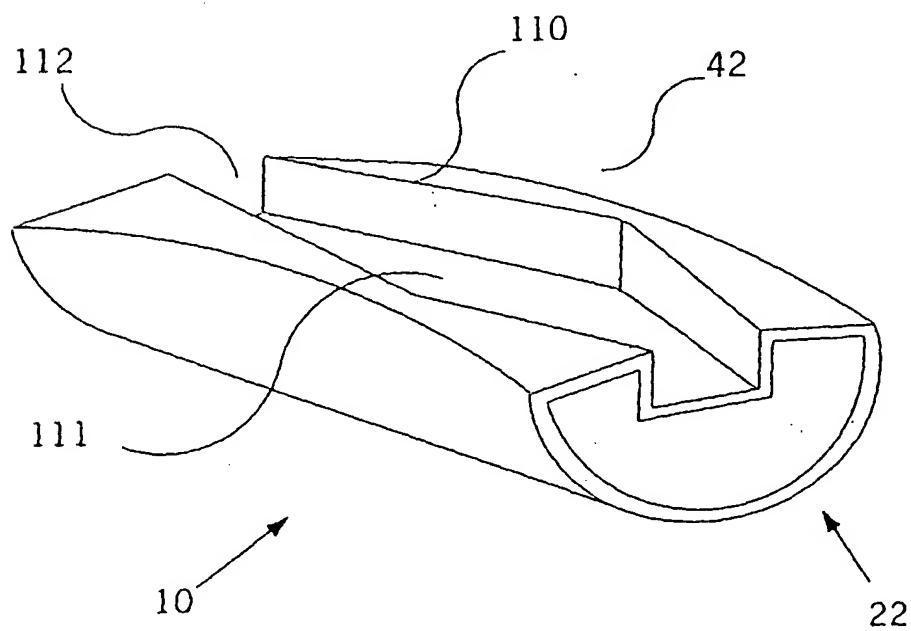


FIG. 15B

11/12

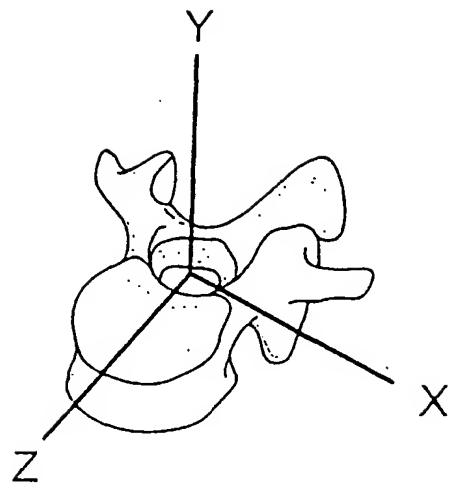


FIG. 16

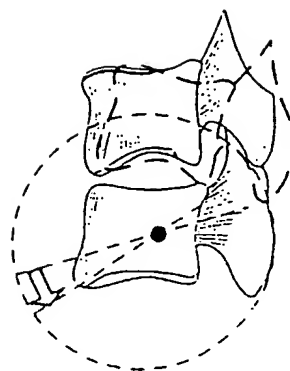


FIG. 17

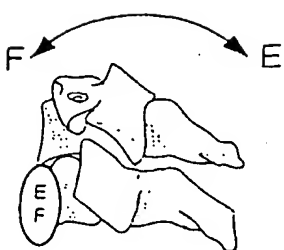


FIG. 18A

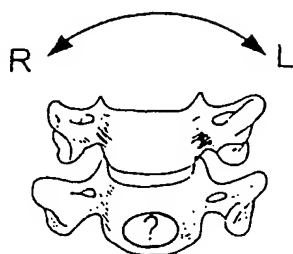


FIG. 18B

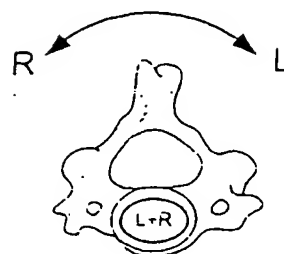


FIG. 18C

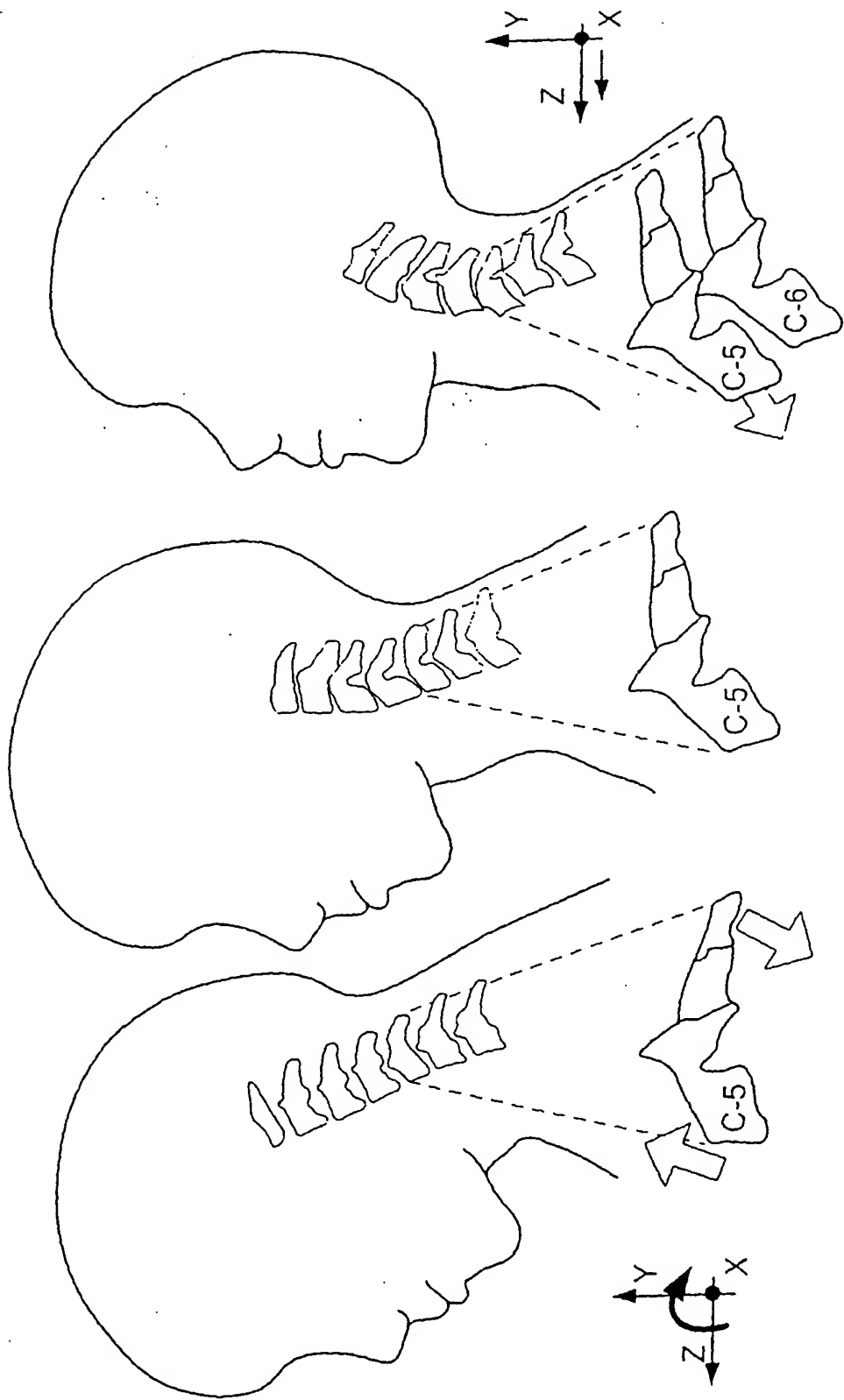


FIG. 19A

FIG. 19B

FIG. 19C

INTERNATIONAL SEARCH REPORT

Int. Application No.

PCT/US 01/06193

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 53871 A (CAUTHEN RESEARCH GROUP INC) 28 October 1999 (1999-10-28) the whole document	1-4, 9-18
A	US 5 782 832 A (SHIKHMAN OLEG ET AL) 21 July 1998 (1998-07-21) the whole document	1
A	US 4 997 432 A (KELLER ARNOLD) 5 March 1991 (1991-03-05) the whole document	1
A	US 5 401 269 A (BUETTNER-JANZ KARIN ET AL) 28 March 1995 (1995-03-28) the whole document	1
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

29 June 2001

Date of mailing of the international search report

11/07/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Korth, C-F

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/06193

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 22 63 842 A (HOFFMANN DAIMLER SIEGFRIED DR) 4 July 1974 (1974-07-04) the whole document ---	1
A	US 4 759 766 A (BUETTNER-JANZ KARIN ET AL) 26 July 1988 (1988-07-26) the whole document ---	1
A	US 5 507 816 A (BULLIVANT MICHAEL) 16 April 1996 (1996-04-16) the whole document -----	1

INTERNATIONAL SEARCH REPORT
Information on patent family members

Int lional Application No
PCT/US 01/06193

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9953871 A	28-10-1999	AU 3758799 A EP 1075236 A	08-11-1999 14-02-2001
US 5782832 A	21-07-1998	AU 4598797 A EP 1009336 A WO 9814142 A	24-04-1998 21-06-2000 09-04-1998
US 4997432 A	05-03-1991	DE 3809793 A DE 58904931 D EP 0333990 A ES 2042814 T US 5122130 A	05-10-1989 26-08-1993 27-09-1989 16-12-1993 16-06-1992
US 5401269 A	28-03-1995	DE 4208116 A AT 144695 T DE 59304327 D EP 0560141 A ES 2094393 T JP 3017371 B JP 6007391 A	23-09-1993 15-11-1996 05-12-1996 15-09-1993 16-01-1997 06-03-2000 18-01-1994
DE 2263842 A	04-07-1974	NONE	
US 4759766 A	26-07-1988	DD 248018 A DD 234609 A DD 239523 A DD 239524 A AT 44871 T CA 1263201 A DE 3529761 A EP 0176728 A JP 2027262 C JP 6105856 A JP 7057229 B JP 1842784 C JP 61122859 A JP 5052218 B	29-07-1987 09-04-1986 01-10-1986 01-10-1986 15-08-1989 28-11-1989 03-07-1986 09-04-1986 26-02-1996 19-04-1994 21-06-1995 12-05-1994 10-06-1986 04-08-1993
US 5507816 A	16-04-1996	AU 2954192 A WO 9310725 A	28-06-1993 10-06-1993